Endoscopy
Smith & Nephew, Inc
150 Minuteman Road
Andover, MA 01810

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978 749 1599 Fax
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We are smith&nephew

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K063467

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

NOV 2 1 2006

Smith & Nephew RF Cannulae
Date Prepared: **October 20, 2006**

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road
Andover, MA 01810

B. Company Contact

Minnie Mildwoff
Regulatory Affairs Specialist
978-7491538 (phone), 978-7491443 (fax)

C. Device Name

Trade Name:	Smith & Nephew RF Cannulae
Common Name:	Probe, Radiofrequency Lesion
Classification Name:	Radiofrequency Lesion Probe

D. Predicate Devices

The Smith & Nephew RF Cannulae is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution: Smith & Nephew RF Probe and Cannulae (K034012).

E. Description of Device

The Smith & Nephew RF Denervation Probe is a temperature sensing electrode designed for use in radiofrequency lesion procedures. The RF Denervation Probe is used with a disposable Smith & Nephew RF Cannula. Smith & Nephew RF Cannulae are offered in a variety of sizes and tip configurations. The RF Cannulae are packaged sterile for single use.

F. Intended Use

Smith & Nephew RF Cannulae are intended to facilitate placement of Smith & Nephew RF Denervation Probes. The Smith & Nephew RF Cannulae are indicated for use in RF heat lesion procedures for the relief of pain.

G. Comparison of Technological Characteristics

The Smith & Nephew RF Denervation Probes & RF Cannulae are substantially equivalent in design, materials, function and intended use to the following device cleared for commercial distribution:

- Smith & Nephew RF Probes and Cannulae – K034012

H. Summary Performance Data

The Smith & Nephew RF Denervation Probes & RF Canulae meet the requirements of electrical safety standards for UL 60601-1 and IEC 60601-1 when used in combination with the Smith & Nephew Electrothermal® 20S Spine System Generator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Smith & Nephew, Inc.
% Ms. Minnie Mildwoff, RAC
Regulator Affairs Specialist
Endoscopy Division
150 Minuteman Road
Andover, Massachusetts 01810

NOV 2 1 2006

Re: K063467
Trade/Device Name: Smith and Nephew RF Cannulae
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency lesion probe
Regulatory Class: II
Product Code: GXI, GXD
Dated: October 23, 2006
Received: October 24, 2006

Dear Ms. Mildwoff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063467

Device Name: Smith and Nephew RF Cannulae

Indications For Use: Smith & Nephew RF Cannulae are intended to facilitate placement of Smith & Nephew RF Denervation Probes. The Smith & Nephew RF Cannulae are indicated for use in RF heat lesion procedures for the relief of pain.

Prescription Use ___X_____ AND/OR Over-The-Counter Use _

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K063467